

CARAFATE- sucralfate 1gm tablet
Advanced Rx Pharmacy of Tennessee, LLC

Sucralfate 1gm tablets #30

Dosage and Administration Section

DOSAGE AND ADMINISTRATION

Active Duodenal Ulcer

The recommended adult oral dosage for duodenal ulcer is 1 g four times per day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

Maintenance Therapy

The recommended adult oral dosage is 1 g twice a day.

Elderly

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see PRECAUTIONS, Geriatric Use).

Call your doctor for medical advice about side effects. You may report side effects to TEVA USA, PHARMACOVIGILANCE at 1-866-832-8537 or drug.safety@tevapharm.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Indications and Usage Section

INDICATIONS AND USAGE

Sucralfate tablets, USP are indicated in:

Short-term treatment (up to 8 weeks) of active duodenal ulcer. While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers.

Principal Display Panel

NDC 0093-2210-98

Sucralfate Tablets, USP 1 gram

Rx only

90 TABLETS

TEVA

Each tablet contains 1 gram
sucralfate.

Usual Dosage: Refer to
package literature for full
prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room
Temperature].

Dispense in a tight,
light-resistant container as
defined in the USP, with a
child-resistant closure (as
required).

KEEP THIS AND ALL
MEDICATIONS OUT OF THE
REACH OF CHILDREN.

Manufactured In Croatia By:
PLIVA HRVATSKA d.o.o.,
Zagreb, Croatia

Manufactured For:
TEVA PHARMACEUTICALS USA, INC.,
North Wales, PA 19454

70048482

Rev. D 9/2015



CARAFATE

sucralfate 1gm tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80425-0091(NDC:0093-2210)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SUCRALFATE (UNII: XX7320 5DH5) (SUCRALFATE - UNII:XX7320 5DH5)	SUCRALFATE	1 g

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	TEVA;22;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0091-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070848	11/11/1996	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0091)

Revised: 11/2020

Advanced Rx Pharmacy of Tennessee, LLC